

**3701:1-66-07      Fluoroscopic radiation-generating equipment.**

For the purposes of this rule, "fluoroscopic equipment" means a type of radiation-generating equipment that is used for real-time imaging of internal structures for medical purpose. In addition to other applicable rules adopted pursuant to Chapter 3748. of the Revised Code, handlers of fluoroscopic equipment shall comply with the following:

- (A) Fluoroscopic equipment shall meet the following standards:
- (1) Unless the United States food and drug administration (FDA) has granted a variance for the specific fluoroscopic equipment, the source-to-skin distance (SSD) shall not be less than:
    - (a) Thirty-eight centimeters on stationary fluoroscopic equipment unless a particular procedure application prohibits that distance, in which case the SSD shall not be less than twenty centimeters.
    - (b) Thirty centimeters on mobile fluoroscopic equipment unless a particular procedure prohibits that distance, in which case it shall not be less than twenty centimeters.
    - (c) Nineteen centimeters for c-arm type fluoroscopic equipment having a maximum source-to-image distance (SID) less than forty-five centimeters unless a particular procedure prohibits that distance, in which case it shall not be less than ten centimeters. Such systems shall be used extremity or dental purposes only.
  - (2) For c-arm fluoroscopic equipment equipped with a removable spacer cone, the spacer cone shall be attached to the x-ray source during use at all times unless it interferes with the clinical procedure.
  - (3) The fluoroscopic imaging assembly shall be provided with a primary protective barrier which intercepts the entire cross-section of the useful beam at any SID and shall prevent further exposures when the primary barrier is not in the path of the entire x-ray beam.
  - (4) All fluoroscopic equipment shall provide intensified imaging. As used in this rule "intensified imaging" will include the use of digital image receptors.
  - (5) Fluoroscopic equipment shall meet the following field limitation specifications:
    - (a) For fluoroscopic equipment manufactured before June 10, 2006, the following applies:
      - (i) Neither the length nor the width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than three per cent of the SID. The sum of the excess length and the excess width shall be no greater than four per cent of the SID.
      - (ii) For rectangular x-ray fields used with circular image receptors, the error in alignment shall be determined along the length and width dimensions of the x-ray field which pass through the center of the visible area of the

image receptor.

- (b) For fluoroscopic equipment with a circular image receptor manufactured on or after June 10, 2006, the maximum area of the x-ray field in the plane of the circular image receptor shall conform with one of the following requirements. When any linear dimension of the visible area of the image receptor measured through the center of the visible area is:
    - (i) Less than or equal to thirty-four centimeters in any direction, at least eighty per cent of the area of the x-ray field shall overlap the visible area of the image receptor; or
    - (ii) Greater than thirty-four centimeters in any direction, the x-ray field measured along the direction of greatest misalignment with the visible area of the image receptor shall not extend beyond the edge of the visible area of the image receptor by more than two centimeters.
  - (c) For fluoroscopic equipment with a rectangular image receptor manufactured on or after June 10, 2006, the following applies:
    - (i) Neither the length nor the width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than three per cent of the SID. The sum of the excess length and the excess width shall be no greater than four per cent of the SID; and
    - (ii) The error in alignment shall be determined along the length and width dimensions of the x-ray field which pass through the center of the visible area of the image receptor.
  - (d) If the fluoroscopic x-ray field size is adjusted automatically as the SID or image receptor size is changed, a capability may be provided for overriding the automatic adjustment in case of system failure. If it is so provided, a signal visible at the operator's position shall indicate whenever the automatic field adjustment is overridden. Each such system failure override switch shall be clearly labeled as follows:
 

"For X-ray Field Limitation System Failure"
  - (e) Beam-limiting devices shall be provided with a means for stepless adjustment of the x-ray field; and
  - (f) Stepless adjustment shall, at the greatest SID, provide continuous field sizes from the maximum obtainable to a field size of five centimeters by five centimeters or less.
- (6) Timers shall meet the following specifications:
- (a) A means shall be provided to preset the cumulative on-time timer of the fluoroscopic tube. The maximum cumulative time of the timer shall not exceed five minutes without resetting; and
  - (b) The timer shall terminate the exposure or emit a signal audible to the operator when the exposure time reaches a maximum of five minutes. The signal shall continue to sound while x-rays are produced until the timer is

reset.

- (c) For x-ray controls manufactured on or after June 10, 2006, there shall be provided for each fluoroscopic tube:
  - (i) A display of the fluoroscopic irradiation time at the operator's working position. This display shall function independently of the audible signal described in paragraph (A)(6)(c)(ii) of this rule. The following requirements apply:
    - (a) When the x-ray tube is activated, the fluoroscopic irradiation time in minutes and tenths of minutes shall be continuously displayed and updated at least once every six seconds.
    - (b) The fluoroscopic irradiation time shall also be displayed within six seconds of termination of an exposure and remain displayed until reset.
    - (c) Means shall be provided to reset the display to zero prior to the beginning of a new examination or procedure.
  - (ii) A signal audible to the operator shall sound for each passage of five minutes of fluoroscopic irradiation time during an examination or procedure. The signal shall sound until manually reset or, if automatically reset, for at least two seconds.
- (7) X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the operator for the entire time of any exposure. When recording serial fluoroscopic images, the operator shall be able to terminate the x-ray exposure at any time, but means may be provided to permit completion of any single exposure of the series in progress.
- (8) Fluoroscopic systems shall meet the following air kerma rate limits:
  - (a) Fluoroscopic equipment provided with only automatic exposure rate control, or provided with both automatic exposure rate control and manual mode capabilities, shall not exceed an air kerma rate of eighty-eight milligray per minute (ten roentgens per minute exposure rate) in either mode at any combination of tube potential and current, at the point where the center of the useful beam enters the patient;
  - (b) Fluoroscopic equipment provided with only manual mode capabilities shall not exceed an air kerma rate of forty-four milligray per minute (five roentgens per minute exposure rate) at any combination of tube potential and current, at the point where the center of the useful beam enters the patient; and
  - (c) For fluoroscopic equipment that is provided with high-level control, and the high-level control is activated, the air kerma rate shall not exceed one hundred seventy-six milligray per minute (twenty roentgens per minute exposure rate) at any combination of tube potential and current, at the point where the center of the useful beam enters the patient;
    - (i) For all fluoroscopy equipment that is provided with high-level control, special means of activation of high level control, such as manual

pressure applied continuously by the operator, shall be required to avoid accidental use; and

- (ii) A continuous signal audible to the operator shall indicate that high level control is being employed.
- (9) During fluoroscopy and cinefluorography the x-ray tube potential and current shall be continuously indicated.
- (10) For undertable fluoroscopic equipment, a shielding device of at least 0.25 millimeter lead equivalent shall cover the bucky-slot.
- (11) For undertable fluoroscopic equipment, protective drapes, or other devices, at least 0.25 millimeter lead equivalent shall be provided between the patient and the individual operating the fluoroscopic equipment to intercept scattered radiation which would otherwise reach the fluoroscopist and others near the x-ray unit, except when such drapes or other devices would compromise the sterile field. Such devices shall not substitute for wearing required protective apparel.
- (12) Radiography using the fluoroscopic imaging assembly shall meet the following specifications:
- (a) A means shall be provided between the source and the patient which will automatically limit the x-ray field at the time the exposure is initiated to no more than the portion of the image receptor selected by the operator. If the x-ray field size is less than the size of the selected portion of the image receptor, the field size shall not open automatically to the size of the selected portion of the image receptor unless the operator has selected such a mode of operation;
  - (b) Neither the length nor the width of the x-ray field in the plane of the image receptor shall differ from the corresponding dimensions of the selected portion of the image receptor by more than three per cent of the SID when adjusted for full coverage of the selected portion of the image selector;
  - (c) The center of the x-ray field in the plane of the image receptor shall be aligned with the center of the selected portion of the image receptor to within two per cent of the SID; and
  - (d) Means shall be provided to reduce the x-ray field size in the plane of the image receptor to a size smaller than the selected portion of the image receptor. The minimum field size at the greatest SID shall not exceed five centimeters by five centimeters.
- (13) Fluoroscopic equipment manufactured on or after June 10, 2006, shall display at the operator's working position the air kerma rate (AKR) and cumulative air kerma in accordance with the following requirements:
- (a) When the x-ray tube is activated and the number of images produced per unit time is greater than six images per second, the AKR in milligrays per minute shall be continuously displayed and updated at least once every second.
  - (b) The cumulative air kerma in units of milligrays shall be displayed either

within five seconds of termination of an exposure or displayed continuously and updated at least once every five seconds.

- (c) The display of the AKR shall be clearly distinguishable from the display of the cumulative air kerma.
  - (d) The AKR and cumulative air kerma shall represent the value for conditions of free-in-air irradiation at one of the following reference locations specified according to the type of fluoroscope.
    - (i) For fluoroscopes with x-ray source below the x-ray table, x-ray source above the table, or of lateral type, the reference location shall be the respective locations specified in paragraphs (C)(6)(a), (C)(6)(b) or (C)(6)(d) of this rule.
    - (ii) For C-arm fluoroscopes, the reference location shall be fifteen centimeters from the isocenter toward the x-ray source along the beam axis. Alternatively, the reference location shall be at a point specified by the manufacturer to represent the location of the intersection of the x-ray beam with the patient's skin.
  - (e) Means shall be provided to reset to zero the display of cumulative air kerma prior to the commencement of a new examination or procedure.
  - (f) The displayed AKR and cumulative air kerma shall not deviate from the actual values by more than plus or minus thirty-five per cent.
- (B) In addition to other applicable radiation safety rules adopted pursuant to Chapter 3748. of the Revised Code, handlers of fluoroscopic radiation-generating equipment shall comply with the following:
- (1) Any individual who is in the room during the fluoroscopic procedure shall be adequately protected by standing behind a whole body protective barrier or shall be required to wear a protective lead apron of not less than 0.25 millimeter lead equivalent.
  - (2) Protective lead or lead equivalent gloves shall be used by individuals who are required to have their hands in or near the useful beam.
  - (3) In accordance with Chapter 3701-72 of the Administrative Code, individuals who perform fluoroscopic procedures on human beings shall hold a radiographer license or shall be a licensed practitioner, except for those individual identified in paragraph (D) of rule 3701-72-04 of the Administrative Code who are limited to performing only the radiologic tasks related to cardiac catheterization procedures as specified in paragraph (D) of rule 3701-72-04 of the Administrative Code. Personnel working for veterinarians that use radiation generating equipment are not required to comply with this paragraph.
  - (4) Handlers of fluoroscopic equipment used for interventional or cardiac procedures or on pediatric or pregnant patients shall maintain a record of:
    - (a) Cumulative air kerma or dose area product used for each examination, if the display of either is available on the fluoroscopic equipment; or
    - (b) The following items if the cumulative air kerma or dose area product is not

displayed on the fluoroscopic equipment:

- (i) Mode of operation such as high-level or pulsed mode;
- (ii) Cumulative fluoroscopic exposure time; and
- (iii) Number of radiographs and number of acquisitions.

(C) In addition to other applicable quality assurance requirements of Chapter 3701:1-66 of the Administrative Code, handlers of fluoroscopic equipment shall comply with the following:

- (1) Handlers shall designate and utilize a radiation expert who shall develop in writing and perform fluoroscopic image quality evaluations appropriate for the fluoroscopic equipment including written procedures to include time intervals and system conditions for the evaluation of image quality.
- (2) On new installations or reinstallations of existing equipment prior to patient exposure, handlers shall utilize a radiation expert to perform the following:
  - (a) Radiographic device tests to determine compliance with allowable limits as specified in paragraph (A)(12) of this rule;
  - (b) Fluoroscopic image quality evaluations as specified in paragraph (C)(1) of this rule; and
  - (c) Air kerma rate tests as specified in paragraph (C)(6) of this rule.
- (3) After initial evaluations of fluoroscopic equipment have been performed, the test and evaluations in paragraph (C)(2) of this rule shall be performed by a radiation expert annually within periods not to exceed fourteen months.
- (4) After repair or replacement of any component of the fluoroscopic equipment which may alter the radiation output or image quality, prior to patient use, a radiation expert shall perform and document measurements of air kerma rates as specified in paragraph (C)(6) of this rule and image quality as specified in paragraph (C)(1) of this rule unless in the documented determination of a radiation expert, the repair or replacement will not cause a significant change in radiation output or significant degradation of image quality as specified in the quality assurance program.
  - (a) The radiation expert may designate qualified individuals to perform and document the measurements specified in paragraph (C)(6) and (C)(1) of this rule;
  - (b) The radiation expert shall provide the criteria for qualifying these designees in the quality assurance program; and
  - (c) The radiation expert's approval of the test results shall be documented.
- (5) The results of all tests performed in accordance with paragraphs (C)(2) to (C)(4) of this rule shall:
  - (a) Include the technique factors used in determining such results;
  - (b) Include the name of the individual performing the measurements;

- (c) Include the date the measurements were performed; and
  - (d) Be maintained by the IRRP between inspections for review by the department.
- (6) Compliance with air kerma rate allowable limits in paragraph (A)(8) of this rule shall be determined as follows:
- (a) If the source is below the x-ray table, the air kerma rate shall be measured at one centimeter above the tabletop or cradle.
  - (b) If the source is above the x-ray table, the air kerma rate shall be measured at thirty centimeters above the tabletop with the end of the beam limiting device or spacer positioned as closely as possible to the point of measurement.
  - (c) For c-arm type fluoroscopic equipment, the air kerma rate shall be measured at thirty centimeters from the input surface of the image receptor with the source positioned at any SID.
  - (d) For fixed SID lateral fluoroscopes attached to the x-ray table, the maximum air kerma rate shall be measured at a point fifteen centimeters from the centerline of the x-ray table and in the direction of the x-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the table top is moveable, it shall be positioned as closely as possible to the lateral x-ray source, with the end of the beam-limiting device or spacer no closer than fifteen centimeters to the centerline of the table.
  - (e) For c-arm type fluoroscopic equipment having a SID less than forty-five centimeters, the air kerma rate shall be determined at the minimum SSD.
  - (f) The maximum air kerma rate shall be determined with the kVp, mA and/or other selectable parameters adjusted to those settings which give the maximum air kerma rate. X-ray systems that incorporate automatic exposure control shall have sufficient attenuative material placed in the useful beam to produce the maximum exposure rate of the system.
- (D) Handlers of mobile fluoroscopic equipment shall not be required to comply with the requirements of paragraphs (A)(10) and (A)(11) of this rule and paragraph (I) of rule 3701:1-66-02 of the Administrative Code.
- (E) Handlers of c-arm fluoroscopic equipment having a maximum SID less than forty-five centimeters shall not be required to comply with the requirements of paragraphs (A)(5)(e), (A)(5)(f), (A)(10), (A)(11), and (A)(12) of this rule and paragraph (I) of rule 3701:1-66-02 of the Administrative Code. In addition, if a radiation expert has specified in the registrant's quality assurance program that an individual is unlikely to receive a total effective dose equivalent of greater than two millirem in any one hour or one hundred millirem in a year, the handler shall not be required to comply with the requirements of paragraph (B)(1) of this rule.
- (F) All individuals operating fluoroscopic equipment, and individuals likely to receive an annual effective dose equivalent in excess of one millisievert (one hundred millirem) from participating in fluoroscopic procedures, shall receive at least two hours of radiation protection training specific to fluoroscopy in addition to the training

required by rule 3701:1-38-10 of the Administrative Code prior to performing or participating in fluoroscopic procedures. Additionally, each individual shall receive one hour of re-training whenever the individual receives in excess of thirty per cent of the allowable occupational dose measured over one calendar year.

- (G) The training required by paragraph (F) of this rule shall be provided by an Ohio registrant, approved by the registrant's designated radiation expert, and be specific to the type of fluoroscopic equipment used. Documentation of receiving the training required by paragraph (F) of this rule shall be retained by the registrant and be available for review upon inspection. At a minimum, training topics shall include, but not be limited to:
- (1) Principles and operation of the fluoroscopic equipment to be used;
  - (2) Fluoroscopic outputs including high-level control options as applicable;
  - (3) Dose reduction techniques for fluoroscopic equipment; and
  - (4) A review of the safe operating procedures of each piece of fluoroscopic equipment that may be used by each individual.
- (H) Fluoroscopic equipment used for radiation therapy simulation is regulated pursuant to rule 3701:1-67-09 of the Administrative Code.
- (I) Computed tomography scanners equipped with fluoroscopic capabilities are regulated pursuant to rule 3701:1-66-10 of the Administrative Code.

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Certification

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